REMARKS

Claims 1-2, 4-20, 25-28, and 30 are pending with claim 1 and 20 being independent. Support for the addition of "and wherein the fast dissolving tablet dissolves in the mouth" is found, for example, at page 2, lines 15-20. This amendment has been incorporated into claims 1 and 20 from canceled claim 3. No new subject matter has been added by these amendments.

Claim 1 is directed to a fast dissolving tablet for oral administration which includes a therapeutically effective amount of one or more drugs that act as a cyclooxygenase-2 ("COX-2") inhibitor, croscarmellose sodium, one or more pharmaceutically acceptable excipients, wherein at least one of the pharmaceutically acceptable excipients is a filler, and wherein the fast dissolving tablet dissolves in the mouth. Claim 20 is directed towards an orally administered, fast dissolving tablet that includes a COX-2 inhibitor, croscarmellose sodium, mannitol, aspartame, colloidal silicon dioxide, magnesium stearate and one or more flavoring agents, and wherein the fast dissolving tablet dissolves in the mouth.

Claims 1-31 have been rejected under 35 U.S.C. §102(b) as being anticipated by Bertelsen et al. (U.S. Patent No. 6,713,089). Claims 1-20, 25-28, 30 and 21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bertelsen et al. (U.S. Patent No. 6,713,089).

Bertelsen discloses an oral modified release pharmaceutical composition suitable for use with drugs that exhibit low solubility in acid environments, namely the stomach. See Col. 1, lines 4-12. The invention has been designed so that the composition releases the drug substance under acidic conditions and is available for absorption in the stomach. See Col. 1, lines 17-21. The pharmaceutical composition "is designed to release at least 50% w/w of the active substance within the first 20 minutes." Col. 9, lines 43-47. Bertelsen provides a "laundry list" of suitable materials, included within are COX-2 inhibitors, such as celecosib and flosulide. Col. 11, lines 1-3. Further provided are extensive lists of pharmaceutically acceptable excipients including fillers, diluents, binders, disintegrants, glidants, lubricants and surfactants. Col. 14, lines 28-67 to Col. 15, lines 1-11.

Applicants respectfully submit that Bertelsen fails to anticipate the present invention because Bertelsen's composition can not dissolve in the mouth, but rather in the acidic environment of the stomach. See Col. 1, lines 4-12. Any reference to an oral modified release composition refers only to the route of administration and not to actual characteristics

of the dosage form. Therefore, Bertelsen does not qualify as anticipatory prior art under 35 U.S.C. §102(b) because it fails to disclose all the elements of the present claims.

Applicants respectfully submit that the rejection of claims 1-20, 25-28, 30 under 35 U.S.C. §103(a) as being unpatentable in view of Bertelsen et al is improper. Bertelsen fails to suggest or provide motivation for a rapidly dissolving tablet for the mouth. Bertelsen's composition dissolves in the stomach and has a dissolution rate of 50% w/w in at least 20 minutes. Col. 9, lines 43-47. All of the disclosure provided in Bertelsen is directed to the use of the oral modified release composition in environments mimicking the stomach. Again, any reference in Bertelsen to an oral modified release composition refers only to the route of administration and not to actual characteristics of the dosage form. Bertelsen provides no motivation or suggestion to one skilled in the art that the composition can be altered or modified to have similar release characteristics as the present invention. Therefore, the rejection of claims 1-20, 25-28, 30-31 as being unpatentable under 35 U.S.C. §103(a) in view of Bertelsen is improper and should withdrawn.

Thus applicants submit that the claims as presented herein are allowable, and respectfully request a Notice of Allowance as the next paper from the Office.

Respectfully submitted,

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